61. (New) The method of claim 48, wherein the composition is in the form of a cosmetic.

62. (New) The method of claim 48, wherein the composition is in the form of a beverage.

63. (New) The method of claim 48, wherein the composition is in the form of a suppository.

64. (New) The method of claim 48, wherein the composition is in the form of a tablet or capsule.

65. (New) The method of claim 48, wherein the cells are liver cells.

66. (New) The method of claim 48, wherein the cells are intestine cells.

67. (New) The method of claim 48, wherein the cells are macrophages.

REMARKS

Claims 1-26 are currently pending. In this Response, Applicant cancels claims 1-26 and replaces the subject matter of elected claims 9-24 and 26 with new claims 27-67. Support for the newly-added limitations to the claims can be found in the original claims (see, for example, claim 13 of the Application) and the specification (such as page 3 of the Application). No new matter has been added.

Applicant thanks the Examiner for the courtesy extended to Applicant's Representative in the personal interviews of August 19, 2002 and October 10, 2002. This Response is directed to the topics discussed in the personal interviews.

In the Office Action, claims 9-24 and 26 were rejected under 35 U.S.C. § 103 as being unpatentable over Fariss (U.S. Pat. No. 5,198,432) by itself or in view of Hendler (U.S. Pat. No. 5,114,957).

This rejection was discussed extensively in the interview of August 19, 2002. As discussed in the personal interview, even assuming arguendo that (1) Fariss broadly discloses that vitamin E phosphate is capable of imparting cytoprotection (see Fig. 4a of Fariss patent) and (2) Hendler broadly teaches the administration of vitamin E phosphate (see column 2, line 63 of Hendler patent) and that the administration may be via a liposome (see column 3, lines 3-4 of Hendler patent), neither of these references teaches the specific liposome constituent claimed in the present case (i.e., polyenylphosphatidylcholine, hereinafter PPC). The Examiner will note that all of the claims in the present case have been limited to the use of PPC as the necessary liposome constituent. Since neither Fariss nor Hendler teach the use of PPC as the necessary liposome constituent, these references cannot render the present invention obvious.

Additionally, as set forth in the Second Declaration (discussed below), the inventive vitamin E phosphate encapsulated in a PPC liposome (VEP/PPC) is not only a potent cytoprotectant, but also actually reverses (repairs) cell damage. Neither Fariss nor Hendler teaches the use of vitamin E phosphate to repair cell damage.

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In the personal interview, the Examiner requested that Applicant submit data showing unexpected results obtained using VEP encapsulated in PPC, as compared to VEP encapsulated in other types of phospholipids, or more specifically, other types of phosphatidylcholine. To that end, Applicant submits herewith a First Declaration Under 37 C.F.R. § 1.132. In this First Declaration, Applicant compares vitamin E phosphate encapsulated in PPC liposomes to vitamin E phosphate encapsulated in egg phosphatidylcholine (EPC) liposomes. As indicated in the First Declaration (a draft of which was shown to the Examiner in the personal interview of October 10, 2002), the inventive VEP/PPC agent is almost five times more effective in protecting against oxidative stress (using ethanol as the oxidative stressor) than VEP/EPC. The results demonstrate that the VEP/PPC of the present Application is inventive due to its completely surprising superiority at protecting cells from injury, as compared to VEP encapsulated in other types of liposome constituents.

At the October 10th personal interview, the Examiner appeared to accept the surprising results of VEP/PPC, as compared to VEP/EPC. However, the Examiner requested that Applicant provide further information regarding the model used in the test (i.e., measurement of changes in cellular PC biosynthesis). In addition, the Examiner requested that Applicant narrow the claims to include those types of cell injuries encompassed by this PC biosynthesis model for determining oxidative stress.

In order to comply with the Examiner's request, Applicant attaches hereto a Second Declaration Under 37 C.F.R. § 1.132 (the Second Declaration). In this Second Declaration, Applicant provides an explanation of the PC biosynthesis model for determining oxidative stress. Applicant also notes herein that this model has been

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validated by the issuance of a U.S. patent therefor, i.e., U.S. Patent No. 6,218,130, which is attached to the Second Declaration. The Second Declaration shows that the PC biosynthesis model is an excellent method for determining oxidative stress.

In accordance with the limitations of this model, Applicant has restricted the claims to include cell damage from oxidative stress. Applicant submits that the claims are now narrowed in scope to the extent supported by the Second Declaration evidence.

The Second Declaration also shows that the inventive composition (VEP/PPC) is at least ten times (and as much as 250 times) more effective than VEP alone or PPC alone in reducing oxidative stress (see, for example, Figures 7 and 9-13 attached to the Second Declaration), a magnitude of difference which is much greater than one would have anticipated by combining VEP and PPC. This result also supports the patentability of the inventive composition.

Applicant respectfully submits that Applicant has complied with all of the Examiner's requests regarding the generation of data showing (a) surprising results of VEP/PPC, as compared to VEP combined with other liposome constituents; (b) a validation of the model used to determine that the inventive composition works in protecting against cell damage from oxidative stress and stimulating repair of cells damaged due to oxidative stress; and (c) confirming VEP/PPC's cytoprotective and repair capabilities beyond injury caused by ethanol to injury caused by oxidative stress.

Applicant respectfully submits that, therefore, the present case is in condition for allowance.

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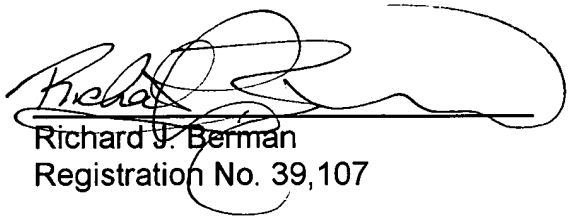
In the event this paper is not timely filed, applicants hereby petition for an appropriate extension of time. The fee for this extension may be charged to our Deposit Account No. 01-2300, along with any other additional fees which may be required with respect to this paper.

Respectfully submitted,



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Enclosures: First Declaration Under 37 CFR 1.132
Second Declaration Under 37 CFR 1.132
Petition for Extension of Time
Amendment and Fee Transmittal

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